HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region M3791n

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6007

May 24, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
George Ajjan, DO
President
Women's Health Care Group, P.C.
870 Palisades Avenue, Suite 305
Teaneck, New Jersey 07666

FILE NO.: 00-NWJ-39
Inspection ID NO.: 1549970006

Dear Dr. Ajjan:

We are writing you because an inspection conducted by the State of New Jersey on behalf of the Food and Drug Administration (FDA) on May 15, 2000, revealed a serious regulatory problem involving mammography at your facility.

Under the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level One deficiencies:

- Phantom Quality Control (QC) records for Unit 3 [redacted] located in the Mammo Room were missing for 12 weeks.

- Phantom QC records for Unit 2 located in the Mammo Room were missing for 6 weeks.

This inspection also revealed the following Level 2 deficiencies:

- Your facility does not have a written procedure for handling consumer complaints.

- Corrective action was not documented for Unit 3 after it obtained a failing image score.

- The Phantom QC was not adequate for Unit 3 because the operating level for the background density was <1.20.

- A medical physicist survey was not conducted for Unit 2 within the last 14 months.

- Corrective actions for Processor QC failures were not documented at least once for Processor 1 ([redacted]).

The specific deficiencies noted above appeared on your MQSA Facility Inspection Report that was issued to your facility at the close of the inspection.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law that may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Mammography Quality Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

You must act on this matter immediately. Please explain or provide to this office in writing within 15 working days from the date that you receive this letter:

- the specific steps you have taken to correct the violations noted in this letter;

- each step your facility is taking to prevent the recurrence of similar violations;

- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and

- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted*).

*This note is not applicable for letters, which also address patient notification.

Please submit your response to Rosa L. Brown, Compliance Technician, Food and Drug Administration, New Jersey District, 10 Waterview Blvd, 3rd Floor, Parsippany, New Jersey 07054.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings disclosed during the inspection of your facility and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have any specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Commander Heywood L. Rourk, Central Regional Radiological Health Representative, at (410) 962-4052.

Sincerely,

DOUGLAS I. ELLSWORTH
District Director
New Jersey District Office

cc: Bureau of Radiological Health
Department of Environmental Protection
P.O. Box 415
Trenton, New Jersey 08625-0415

Pamela A. Wilcox-Buchalla, R.N., M.B.A.
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RLB/

Bcc: HFI-35 (FOI Staff - stamped & purged copy)
HFA-224
HFC-210 (Division of Compliance Policy)
HFC-240 (Medical Products Quality Staff)
HFZ-240
HFZ-322
HFR-CE250 (H.L. Rourk)
EF (Women's Health Care Group, Teaneck, NJ)
HFR-CE350 [Gp4 (T. Williams)]
HFR-CE340 (DCBr/RLB/WL File/Legal File)

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